

Action Information

Action Title: Pesticides; Draft Guidance for Pesticide Registrants on Plant Regulator Label Claims, including Plant Biostimulants; Notice of Availability (Tier 3; SAN 5840)

Purpose: This document is intended to provide guidance on identifying product labeling claims considered to be plant regulator claims by the Agency, thereby subjecting the products to regulation under FIFRA as pesticides. Examples are provided of both claims that are considered plant regulator claims and claims that are not considered plant regulator claims. The guidance does not address or attempt to provide a regulatory definition for “plant biostimulant” or for “nutritional chemical.”

Background: Plant biostimulants (PBS) are a relatively new, but growing, category of products containing naturally-occurring substances and microbes that are used to stimulate plant growth by enhancing water and nutrient use efficiency, and reducing abiotic stress. The increasing popularity of PBS arises from their ability to enhance agricultural productivity by stimulating natural processes in the plant and in soil using substances and microbes already present in the environment. PBS can promote greater water and nutrient use efficiency, but do not provide any nutritionally-relevant fertilizer benefit to the plant. PBS products are becoming increasingly attractive for use in sustainable agriculture production systems and integrated pest management (IPM) programs, which in turn can reduce the use of irrigation water, as well as agrochemical supplements and fertilizers.

Key Issues/Internal Review: This action has been identified by OMB as a significant guidance document under Executive Order 12866, and will therefore undergo OMB review. As a result, a Final Agency Review (FAR) will be held with the following offices with workgroup participation; OGC, OP, OECA, and ORD. A draft has also been provided to the Regions, with their feedback having been incorporated into the draft.

Estimated Cost Savings/Burden Reductions: EPA anticipates that this guidance will eliminate ambiguity and provide regulatory clarity, help to specify products and labeling claims that may require registration, and reduce regulatory burden on industry. Cost savings are not quantifiable; as industry grows, regulatory clarity increases in value. Savings are mostly intangible (less effort to determine appropriate regulatory path). Additionally, this guidance is expected to help avoid delays in marketing, even recalls, and to help avoid label redesign/reprinting costs. There are also expected to be savings for state regulatory agencies by providing clarity on products not needing registration.

Stakeholder Involvement: During the development of this draft guidance document, EPA discussed this new approach the Association of American Plant Food Control Officials (AAPFCO), the Biological Products Industry Alliance (BPIA), the United States Biostimulants Coalition (USBC), and the State FIFRA Issues Research and Evaluation Group (SFIREG). Additional feedback was received at various technical PBS conferences, such as the Third World Biostimulants Congress and Crops & Chemicals Conferences.

Deadlines: There are no judicial or statutory deadlines associated with this draft guidance.

Timing: EPA’s current schedule provides a 15-day FAR in June 2018 and 90-day OMB review starting in August 2018. A FRN providing a 60-day comment period on the draft guidance is currently projected for the Administrator’s signature in December 2018/January 2019.

May 10, 2018

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